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13. ABSTRACT ***(Maximum 200 Words)***

Epithelial ovarian cancer continues to be the leading cause of death from gynecologic cancer in the United States and is responsible for over 14,500 deaths per year. The availability of cancer risk counseling and genetic testing for *BRCA1* and *BRCA2* have prompted increasing numbers of women to seek information about their ovarian cancer risk estimation and advice on risk reduction strategies. Because effective methods for early detection are so limited, primary prevention options are actively being sought. A primary surgical preventive option being considered by increasing numbers of women is prophylactic oophorectomy, a procedure that can now be performed laparoscopically with minimal surgical morbidity. However, little data exists on the long-term physical, psychological and social consequences of such surgery. Identifying the quality of life issues following oophorectomy through this pilot study will foster a better understanding of the multidimensional process experienced by women in this situation, in order to better address their needs and to facilitate effective preventive actions.

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INTRODUCTION

Awareness of the risk factors related to ovarian cancer and the contribution of genetics is increasing both within the lay and professional communities. Cancer control for ovarian cancer is moving into a promising era with surgical options showing potential for significant risk reduction for developing the disease. With the availability of cancer risk counseling and genetic testing for *BRCA1* and *BRCA2*, increasing numbers of women are seeking information about their own cancer risk and advice on prophylactic oophorectomy. As this awareness regarding the major risk factors for ovarian cancer, i.e., family history, genetic susceptibility, and personal history of early onset breast cancer continues to increase, it is our experience in the Family Risk Assessment Program at Fox Chase Cancer Center that a proportion of our participants are considering preventive surgery. However, little data exists on the long-term physical, psychological and social consequences of prophylactic oophorectomy. Most related studies have examined the effects of ovarian function loss from hysterectomy or cancer treatment and have focused on very limited quality of life outcomes. To meet the needs of women seeking information about the effects of prophylactic oophorectomy and for those who will undergo the procedure, this study will provide significant information on the broader quality of life domains and physiologic changes following surgery. In order to make informed decisions about their choices, women considering prophylactic oophorectomy need scientific data on the hormonal and other physiologic consequences of surgery, and on the potential alterations in their emotional and social well being. They also need the opportunity to choose from an array of coping strategies to manage their health decisions. Ovarian cancer advocacy groups have voiced their support for research that advances not only ovarian cancer prevention and treatment but also quality of life. Studying multidimensional quality of life issues will contribute to the knowledge base about the short and long-term effects on physical, emotional, cognitive, sexual and social functioning following oophorectomy and will contribute to the development of optimum medical and alternative therapy strategies to deal with post-surgical sequelae. As important, it will also identify issues and needs faced by women who make the choice not to undergo surgery. Identifying the quality of life issues following oophorectomy will build on foundational ovarian cancer research currently underway through the Department of Defense grant-funded "Ovarian Cancer Prevention Program."

BODY

The following describes the progress during the past year associated with each task in the Statement of Work.

Task 1: Creation of Participant Advisory Board

In order to be flexible and accommodate diverse scheduling needs we have adopted a more informal advisory approach. Consultations have been held by telephone with Drs. Electra Paskett and Brigitte Miller at Wake Forest University Baptist Medical Center and in person with Dr. Cynthia Bergman here at Fox Chase Cancer Center to discuss recruitment strategies and challenges to accrual. We have also been in contact with the collaborating sites' project managers in the DOD-funded Ovarian Cancer Consortium for Research and Surveillance to enlist their assistance in study development and recruitment. We have an ongoing relationship

with a local advocacy group, the Philadelphia chapter of the National Ovarian Cancer Coalition, and have explored collaboration with them. Cindy Melancon, RN, highlighted a notice about this research opportunity in her *Conversations! The Newsletter for Those Fighting Ovarian Cancer* April 2001 issue. Dr. Carolyn Fang of the Behavioral Science Program at Fox Chase Cancer Center has been consulted regarding collaborative recruiting procedures.

Task 2: Selection of Survey Instruments

All study instruments have been finalized and were approved by the IRB. Outcome variables include physical functioning, menopausal symptoms, body image, sexual functioning, anxiety, depression, and use of pharmaceutical, dietary and alternative therapies. The instruments being used are as follows:

1. The NSABP BCPT Quality of Life Questionnaire. This instrument was used by over 13,000 women in the Tamoxifen prevention trial. It includes the Medical Outcomes Study (MOS) 36-item short form, a generic measure of health-related QOL, the Center for Epidemiologic Studies-Depression Scale, used widely in community epidemiologic studies, the MOS sexual problems scale, and a 43-item symptom checklist of commonly reported physical and psychologic symptoms, as well as symptoms associated with the menopause, including the domains of vasomotor symptoms, vaginal dryness, sexual functioning, sleep disturbance and cognitive functioning. Sleep patterns and sleep quality may be disrupted by surgical menopause. This questionnaire will be collected at all time points.
2. Post-Surgical Expectations Questionnaire. The NSABP BCPT Quality of Life Questionnaire has been modified to assess women's expectations of menopausal symptoms they anticipate experiencing following oophorectomy. It includes an open-ended response format as well as a Likert-type summary scale of symptoms. This questionnaire will only be assessed at baseline, prior to surgery.
3. Fallowfield Sexual Activity Questionnaire (SAQ). This tool is a validated measure for describing the sexual functioning of women in terms of activity, pleasure and discomfort. It was developed to investigate the impact of long-term Tamoxifen usage on the sexual functioning of women at high risk of developing breast cancer. This measure will be collected at all time points.
4. Self Concept Scale. This 10-item scale assesses the participants' satisfaction with different areas of their body and their overall weight. Persons undergoing oophorectomy may experience an alteration in their perception of their body image which may affect their psychosocial status and intimate relationships. This scale was developed by Dr. David Cella, (Director, Center on Outcomes Research and Education, Evanston Hospital) through his work with breast cancer patients. It will be collected at all time points.
5. Medical/Dietary Supplement Survey. This survey elicits use of hormone replacement therapy, dietary supplements, micronutrients, as well as exercise, yoga, meditation, and other forms of coping strategies. The survey has been piloted among 48 women in the FRAP program for feasibility and ease of administration. Overall, we found that 89% of the women surveyed took some form of dietary supplement. It will be collected at all time points.

6. Post-Surgery Satisfaction Questionnaire. Patients' levels of satisfaction with oophorectomy will be assessed using three items rated on a 5-point Likert-type scale. Scores from the three items will be combined to form a composite index of satisfaction. It will be collected at all post-surgery time points.
7. Medical Outcomes Survey. This survey will capture information on new medical diagnoses, procedures, and screening exams at the 12-month follow-up time point. It will be adapted from our current FRAP annual follow-up questionnaire.

Task 3: Development of a Recruitment Strategy

Eligibility guidelines have been finalized to include women, age 25 and older who are considering prophylactic oophorectomy due to: 1) a family history of ovarian cancer, 2) a family history suggestive of a hereditary breast/ovarian pattern and/or 3) the presence of a known disease-related mutation in the family (although eligibility will not be confined to mutation-positive women). All study documents including informed consent form are IRB approved.

Participants have been identified through existing components of the Family Risk Assessment Program (FRAP) which include: 1) an initial health history questionnaire in which it is asked if the person has considered prophylactic oophorectomy, 2) through the cancer risk counseling sessions where preventive options are discussed and 3) through the FRAP clinic where women have physical exams and further discuss screening and prevention. While a significant percentage of participants in the FRAP program consider surgery, it is our experience that the decision to proceed is a lengthy process, often taking months or years. This presents a practical challenge to recruiting the control arm in that it is difficult to identify a point in time when women decide against surgery. We have queried our FRAP database for potentially eligible women based on mutation testing and are currently devising a plan to contact them via a letter that will be submitted to the IRB for approval.

Additional pages to the FRAP section of the Fox Chase Cancer Center website, http://www.fccc.edu have been designed to further aid recruitment. Final adjustments are being made and the content will be forwarded to the IRB shortly.

Recruitment notices have been placed in the FRAP newsletter, *Prevention Matters*, and in *Conversations! The Newsletter for Those Facing Ovarian Cancer.* To date 25 women have been recruited into the study, 20 having had surgery and five considering the decision.

Task 4: Creation of Data Entry Screens, Data Editing Program

Appropriate data entry screens have been designed and are in use. Data is entered promptly and close consultation between the project manager and data entry clerk has served to oversee data editing review. A series of edit checks and quality assurance measures take place on a routine basis whenever data is entered into our bioinformatics system.

Tasks 5 & 6: Conduct Baseline & Follow-up Surveys

Surveys are sent in packets with an instruction cover letter and postage paid return envelope. The project manager receives an email notice to trigger the sending of packets. Reminder postcards and personal phone calls are made when warranted to alert participants of overdue surveys.

Task 7: Data entry, data analysis

Data entry is up to date. The project manager tracks study accrual and questionnaire completion on a biweekly basis. Data analysis has not yet been performed.

Task 8: Report, manuscript preparation.

The required report for ongoing review by the Research Review and IRB committees at Fox Chase Cancer Center was prepared and approved on 5/31/01 and 6/26/01, respectively. Insufficient data exists at this time for manuscript preparation.

KEY RESEARCH ACCOMPLISHMENTS

None to date.

REPORTABLE OUTCOMES

None to date.

CONCLUSIONS

As data has not been analyzed at this point there are no study conclusions. We will adjust our recruitment plan so as to accrue sufficient numbers for meaningful outcomes. The expectation remains that the information learned will be valuable in counseling women who are considering prophylactic oophorectomy as an ovarian cancer risk reduction strategy.

REFERENCES

None.

APPENDICES

None.